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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/620,641	07/16/2003	Wayne V. Vedeckis	Vedeckis 97M20-D	1702

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PATENT DEPARTMENT
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EXAMINER	
BASI, NIRMAL SINGH	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 11/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/620,641	VEDECKIS ET AL.	
	Examiner	Art Unit	
	Nirmal S. Basi	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *31 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,7,14,15 and 19* is/are pending in the application.

4a) Of the above claim(s) *14,15 and 19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 July 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/16/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Amendments filed 7/16/03 and 8/31/06 have been entered.

2. IDS filed 7/16/03 has been entered. Applicant provided no references.

3. Applicant's election with traverse of Group I (Claims 1-4 and 7) on 8/31/06 is acknowledged. Applicant traverses the restriction of Group I from Group V and Group VIII. Applicant argues, "The Office gave as an example of another use for the product of Group I: "the nucleic acids of Group I can be used to produce the encoded protein, which in turn can be used for the production of antibodies." Applicants submit that this example is not a bona fide, real world "materially different process" for the use of the product. Applicant also argues, "A generic use of a product that is non-specific and insubstantial does not meet the Office's burden to give an example of a materially different process as required by M.P.E.P § 806.05(h)". Applicant's arguments have been fully considered but not found persuasive. The M.P.E.P § 806.05(h) states, "If the applicant either proves or provides a convincing argument that the alternative use suggested by the examiner cannot be accomplished, the burden is on the examiner to support a viable alternative use of withdraw the requirement". The nucleic acid of Groups I and VI can be used to produce the encoded protein, which, in turn, can be used to raise antibodies. The production of protein using the polynucleotide is routine in the art. The production of antibodies is also routine in the art. Applicant has not provided any arguments showing the alternative use suggested by the examiner cannot be accomplished. Further the nucleic acid of Group I and VI can be used to produce primers or in hybridization assays to detect complementary strands.

Applicant argues the Office did not state why groups I and V are distinct. The compounds of Group I and the methods of group V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids of invention I can be used to: a) produce the encoded protein, which in turn can be used for the production of antibodies, b) the nucleic acid of Group I can be used to produce primers, or c) the nucleic acid of Group I in hybridization assays to detect complementary strands. Further, the remaining Groups I, V and VIII are classified under a different class/subclass and an examination of the materially different, patentably distinct inventions in a single application would constitute a serious undue burden on the examiner.

Claims 14-15 and 19 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

The requirement is still deemed proper and is therefore made FINAL.

Response to request the Group I be rejoined with Group VI and Group VIII

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final

rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-4 and 7 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 1-3 recite an hGr 1Ap/e gene but do not recite that it is isolated or purified. The claims as currently recited encompass these naturally occurring compounds. Therefore, the compounds as claimed are a product that occurs in nature and does not show the hand of man, and as such is non-statutory subject matter. It is suggested that the claims be amended to recite "an isolated and purified" hGr 1Ap/e gene to overcome this rejection.

Claim 4 recites "A human glucocorticoid receptor exon IA region "hGr 1Ap/e gene" but does not recite that it is isolated or purified. The claims as currently recited encompass these naturally occurring compounds. Therefore, the compounds as claimed are a product that occurs in nature and does not show the hand of man, and as such is non-statutory subject matter. It is suggested that the claims be amended to recite "an isolated and purified" human glucocorticoid receptor exon IA region "hGr 1Ap/e gene to overcome this rejection.

Claim 7 recites "A mRNA transcript" but does not recite that it is isolated or purified. The claims as currently recited encompass these naturally occurring compounds. Therefore, the compounds as claimed are a product that occurs in nature and does not show the hand of man, and as such is non-statutory subject matter. It is suggested that the claims be amended to recite "an isolated and purified" mRNA to overcome this rejection.

Objections

5. Applicants are required to use the heading "Brief Description of the Drawings" to describe the drawings. See MPEP 608.01(f). On page 7, Applicant has written "Description of the Drawings".

Appropriate correction is required.

6. The disclosure is objected to because of the following informalities:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification (37 CFR 1.78) as well as the relationship of instant application to the parent. The reference to the prior application(s) is not contained in the first sentence of the specification. In instant case the reference to the prior application(s) follows:

"Wayne V. Vedeckis and Mary B. Breslin

Express Mail No. EK968023137

File No. Vedeckis 97M20-D"

Appropriate correction is required.

7. Claims 2 and 3 are objected to because of the following informalities: Claims 2, 3 and 7 are confusing because the numbering of the nucleotides in Figure 1 and SEQ ID NO:1 is not consistent. In claim 2 applicant has referred to the numbering of nucleotides in both Figure 1 (position -1075 to position -1) and SEQ ID NO:1 (it appears this corresponds is position 1 to position1075) . In claims 3 and 7 applicant has referred to the numbering of nucleotides in both Figure 1 (position +1 to position+981) and SEQ ID NO:1 (it appears this corresponds is position 1076 to position 2056). Since the numbering of the nucleotide in Figure 1 and SEQ ID NO:1 is different, it is suggested

that the claims be amended to refer to the regions (nucleotide positions) in SEQ ID NO:1 to overcome the objection. Referring to the numbering in Figure 1 and the nucleotides in SEQ ID NO:1 makes the claims confusing. Further, since the examiner will be using the sequence disclosed in SEQ ID NO:1 for a prior art search there must be no ambiguity as to the numbering.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant specification does not contain a written description of the invention in such full, clear, concise, and exact terms or in sufficient detail that one skilled in the art can reasonably conclude that applicant had possession of the claimed invention at the time of filing.

The claims are directed to an hGR 1Ap gene for the human glucocorticoid receptor promoter 1A and Exon 1A comprising at least 2056 bases of SEQ ID NO:1.

The specification discloses the nucleic acid of SEQ ID NO:1, which consists of the promoter region (nucleotides 1-1075) and coding region of exon 1A of the

glucocorticoid receptor (nucleotides 1076-2056).

The disclosure of one region of the hGR 1Ap gene encoding a polypeptide does not adequately describe the scope of the claimed genus of "gene", which encompasses polynucleotides comprising other undisclosed exons and introns. A description of a genus of polynucleotides may be achieved by means of a recitation of a representative number of polynucleotides, defined by the polynucleotide sequence, falling within the scope of the genus or of a recitation of structural and functional features common to members of the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The specification fails to provide sufficient descriptive information, such as definitive structural and functional features of the claimed genus of polynucloeotide/nucleic acids. There is no description of the intron and exon structure of the claimed polynucleotide

An adequate written description of a gene, requires a precise definition, such as by structure, formula and chemical name not a mere wish or plan for obtaining the claimed chemical invention. Accordingly, an adequate written description of the gene is more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the gene itself. Accordingly, the specification does not provide a written description of the invention of claims 1-4.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the

'written description' inquiry, *whatever is now claimed.*" (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (*See Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see page 115). Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The nucleic acid or polypeptide is itself is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

Furthermore, In *The Reagents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement, which defines a genus of nucleic acids by only their functional activity, does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA...'requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention".

It does not appear that Applicants were in possession of scope of the "gene" or genomic polynucleotide as claimed at the time the invention was made. There is no guidance provided to allow the skilled artisan to predict the structure of the gene other

than that of SEQ ID NO:1. Even though the polynucleotide of SEQ ID NO:1 may be part of a genomic DNA segment, what besides the polynucleotide of SEQ ID NO:1 is present is not know. Due to their nature, genes are very complex structures, which are made of coding and non-coding regions (exons and introns, respectively). One skilled in the art could not predict either the number or position of introns or additional exons in the claimed genomic polynucleotide or their nucleic acid sequences. Even assuming high skill of the artisan, one could not predict if there are additional coding regions in the claimed genus of variants and framents comprising genomic DNA, beside that which is shown in SEQ ID NO:1.

With the exception of SEQ ID NO:1, the skilled artisan cannot envision the detailed chemical structure of the gene claimed and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016.

One cannot describe what one has not achieved. See Fiddes v. Baird, 30 USPQ2d 1481, 1483. In Fiddes v. Baird, claims directed to mammalian FGFs were found unpatentable due to lack of written description for the broad class.

Therefore, only the isolated nucleic acid comprising the polynucleotide sequence of the hGR 1Ap human glucocorticoid receptor promoter 1A and Exon 1A disclosed in

SEQ ID NO:1 but not the full breadth of the claim meets the written description provision of 35 U.S.C. 112, first paragraph.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-4 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Encio et al (The journal Of Biological Chemistry, Vol. 266, No.11, April 15, 1991, pages 7182-7188, see IDS).

Encio discloses genomic structure of human Glucocorticoid receptor from genomic libraries and IMg cells. Although the specific sequence of SEQ ID NO:1 is not disclosed the IMg cell inherently contains the claimed glucocrticoid receptor gene and mRNA transcript. The naturally occurring compounds encompassed by the claims are inherently contained in the cells disclosed by Encio. Note the specification, page 17, discloses that GR protein and its mRNA are found in all cell types.

10. No claim is allowed.

Advisory

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nirmal S. Basi whose telephone number is 571-272-0868. The examiner can normally be reached on 9:00 AM-5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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